REMARKS

The present Amendment responds to the Office Action mailed December 23, 2008. Claims 12-14, 18-22, 58-66 were pending in the application. Claims 12-14, 18-22, 58-66 are now pending for reconsideration without amendment.

Summary of the Office Action

In the Office Action: Claims 12-14, 18-20 and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,205,284 to Freeman. Claims 59, 61-64 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,320,642 to Scherlag in view of U.S. Patent No. 4,402,322 to Duggan. Claims 58, 60, 65, 66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,320,642 to Scherlag in view of U.S. Patent No. 4,402,322 to Duggan and further in view of U.S. Patent No. 5,374,282 to Nichols *et al.* These rejections are respectfully traversed based upon the following remarks.

Response to Rejections of Claims 12-14, 18-20 and 22

In the Office Action mailed on May 20, 2008, the Examiner asserts that Freeman is considered to anticipate all of the subject matter of the above referenced claims. The Examiner reasons that Freeman anticipates the present invention because Freeman shows circuitry which can produce subthreshold anodal stimulation and subthreshold pacing pulses. Applicant respectfully disagrees.

Claim 12, which is currently pending is noted below:

> 12. (Previously Presented) Apparatus comprising circuitry for creating a non-excitatory electric potential between at least two points located in the vicinity of a muscle, comprising circuitry for controlling the start time and/or the duration of the electric potential generated between said at least two points which is synchronized to heart activity, said non-excitatory electric potential being a first phase of a bi-phasic pacing pulse. (Emphasis added by underlining.)

Claims 13, 14, 18-20, and 22 have similar claim elements.

Freeman's invention relates to pacing the heart transcutaneously. In Freeman's invention, because pacing pulses must pass through the skin and skeletal muscles before reaching the heart, Freeman describes a method to reduce the effect of the pacing pulses on the patient's skin and the skeletal muscles. See, Freeman, Col. 5, Lns. 22-26. In doing so, Freeman uses biphasic pulses as *background pulses* to reduce the patient's discomfort and painful reactions (e.g. skeletal muscle contraction) to pacing pulses that pass through the patient's skin and skeletal muscles before reaching the patient's heart. These biphasic background pulses were not intended to stimulate the heart.

In fact, Freeman teaches away from using biphasic background pulses, which include anodal stimulation, in stimulating the heart because they may cause cardiac fibrillation. Freeman discloses that "background pulse trains, . . . are delivered only to the skin and skeletal muscles, and not to the heart. This electrode configuration ensures that cardiac fibrillation will not be induced by the background pulse trains." See, Freeman, Col. 6, Lns. 5-9. (Emphasis added by underlining.)

In summary, not only does Freeman not disclose biphasic stimulation in pacing a patient's heart, but Freeman teaches away from applying such biphasic stimulation (i.e. excitatory and non-excitatory pulses) to the heart because it may cause cardiac fibrillation.

In contrast, the currently pending claims use biphasic pulses (i.e. cathodal excitatory and anodal non-excitatory pulses) in pacing the heart. Accordingly, Applicant respectfully requests that the Examiner withdraw this rejection and favorably reconsider claims 12-14, 18-20 and 22.

Response to Rejection of Claims 58-66

The Examiner alleges that Scherlag teaches the ability to stimulate the heart with excitatory pulses as well as non-excitatory pulses and that the non-excitatory stimulation has an amplitude below a level needed to excite tissue. The Examiner further alleges that Duggan teaches biphasic stimulation of a patient's heart. Applicant respectfully disagrees.

Claim 58, which is currently pending is noted below:

58. (Previously Presented) Apparatus for heart pacing with cardiac output modification,

comprising:

one or more electrodes adapted to apply electrical signals to cardiac muscle segments;

signal generation circuitry adapted to apply an excitatory electrical pulse to at least one of the one or more electrodes to pace the heart and an anodal non-excitatory stimulation pulse of a magnitude and at a timing at which it is unable to generate a propagating action potential to at least one of the one or more electrodes to modify the cardiac output; and

at least one pressure sensor which senses cardiac activity, wherein the sensor is coupled to the signal generation circuitry, which generates the pulses responsive thereto.

(Emphasis added by underlining)

Claims 59-66 have similar claim elements. Scherlag discloses a method for alleviating heart block by delivering a subthreshold stimuli to the heart. Scherlag uses a stimulus to excite the pacemaker cells in the heart. In doing so, Scherlag applies enough stimulus to excite the pacemaker cells without exciting the heart muscles. In other words, Scherlag first uses suprathreshold stimulation (stimulation that causes heart muscles to contract) to identify a heart muscle stimulation threshold, and then adjusts the pulses to a *subthreshold* level (stimulation that would excite the pacemaker cells but not the myocardial cells) to deliver electrical signals through a damaged His bundle. See, Scherlag, Col. 2, Lns. 23 – 40. In summary, Scherlag uses conventional stimulation methods to determine a subthreshold level to apply and does not teach biphasic (i.e. non-excitatory and excitatory) stimulation of the myocardial cells. Duggan also fails to teach biphasic stimulation of myocardial cells. Duggan merely uses conventional bipolar leads in stimulating the heart. There are two major types of lead systems that are used in delivering electrical pulses to the heart: Unipolar and Bipolar. A unipolar lead system has only one electrode on the lead itself: the cathode, or active pole. Current flows from the cathode, stimulates the heart, and returns to the anode on the casing of the pulse generator to complete the circuit. A bipolar lead has two poles on the lead a short distance from each other at the distal end, and both electrodes lie within the heart.

A major disadvantage of unipolar pacing is the proximity of skeletal muscle to the anode plate. Frequently, local skeletal muscle contraction occurs when current is returning to the anode after myocardial stimulation. Because of the proximity of the cathode and anode leads in a bipolar electrode the circuit can be completed without discomfort to the patient. In contrast, the present invention uses biphasic stimulation of the heart which includes excitatory and non-excitatory pulses.

In summary, both Scherlag and Duggan use conventional pacing methods and fail to disclose biphasic (i.e. excitatory and non-excitatory) stimulation of the heart. Accordingly, Applicant respectfully requests that the Examiner withdraw this rejection and favorably reconsider the claims.

Conclusion

For the above reasons it is respectfully submitted that the claims as previously submitted are allowable.

Request for Interview

In the event that the Examiner feels that the above arguments are not sufficient to overcome the current claim rejections, or if some slight change in claim scope would render the claims as previously submitted allowable, Applicant requests the courtesy of either an in-person meeting or an examiner's amendment to resolve any further issues.

Respectfully submitted,

Jon L. Roberts, Ph.D., J.D.
Registration No. 31,293
MARBURY LAW GROUP, PLLC
11800 Sunrise Valley Drive, Suite 1000
Reston, VA 20191-5302
(703) 391-2900